



General

Guideline Title

Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians.

Bibliographic Source(s)

Qaseem A, Humphrey LL, Forciea MA, Starkey M, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2015 Mar 3;162(5):370-9. [110 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the overall quality of evidence (high, moderate, low, or insufficient evidence to determine net benefits or risks) and the strength of the recommendations (strong, weak) are provided at the end of the "Major Recommendations" field.

Recommendation 1: American College of Physicians (ACP) recommends that clinicians use protein or amino acid supplementation in patients with pressure ulcers to reduce wound size. (Grade: weak recommendation, low-quality evidence)

Evidence showed that nutritional supplementation with protein or amino acids reduced pressure ulcer wound size, but evidence for the optimal dose or form of protein was insufficient. Protein supplementation was assessed in conjunction with standard therapies, such as dressings or support surfaces. Also, the trials generally included patients with nutritional deficiencies, and the evidence may not be generalizable to all patients with pressure ulcers because they may not benefit from nutritional supplementation. Evidence also did not show any benefit of vitamin C supplementation compared with placebo. Data are insufficient to comment on complete wound healing. The relationship between reduction in wound size or rate of healing and eventual complete healing has not been well-defined.

Recommendation 2: ACP recommends that clinicians use hydrocolloid or foam dressings in patients with pressure ulcers to reduce wound size. (Grade: weak recommendation, low-quality evidence)

Low-quality evidence showed that hydrocolloid dressings are better than gauze dressings for reducing wound size. In addition, moderate-quality evidence showed that hydrocolloid dressings resulted in complete wound healing similar to that of foam dressings (hydrocellular or polyurethane). Evidence was insufficient to determine whether specific dressings resulted in fewer harms than others. Data are insufficient to comment on complete wound healing. The relationship between reduction in wound size or rate of healing and eventual complete healing has not been well-defined.

Recommendation 3: ACP recommends that clinicians use electrical stimulation as adjunctive therapy in patients with pressure ulcers to accelerate wound healing. (Grade: weak recommendation, moderate-quality evidence)

Moderate-quality evidence supports the use of electrical stimulation in addition to standard treatment because it has been shown to accelerate the healing rate of stage 2 to 4 ulcers. Data are insufficient to comment on complete wound healing. The relationship between reduction in wound size or rate of healing and eventual complete healing has not been well-defined. The Figure in the original guideline document summarizes the recommendations and clinical considerations.

Definitions:

Grading of Quality of Evidence

High-Quality Evidence: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change confidence in the estimate of effect.

Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on confidence in the estimate of effect and may change the estimate.

Low-Quality Evidence: Evidence obtained from observational studies would typically be rated as low quality because of the risk for bias. Low-quality evidence means that further research is very likely to have an important effect on confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

The American College of Physicians' Guideline Grading System*

Quality of Evidence	Strength of Recommendation	
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	Benefits Finely Balanced With Risks and Burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or risks		

*Adopted from the classification developed by the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) workgroup.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pressure ulcers

Guideline Category

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Nursing

Intended Users

Advanced Practice Nurses

Dietitians

Hospitals

Nurses

Physical Therapists

Physician Assistants

Physicians

Guideline Objective(s)

To present the evidence and provide clinical recommendations based on the comparative effectiveness of treatments for pressure ulcers

Target Population

Patients with pressure ulcers

Interventions and Practices Considered

1. Protein or amino acid supplementation
2. Use of hydrocolloid or foam dressings to reduce wound size
3. Electrical stimulation (adjunctive therapy)

Major Outcomes Considered

- Complete wound healing and wound size (surface area, volume, and depth) reduction
- Additional outcomes include:
 - Pain
 - Prevention of sepsis
 - Prevention of osteomyelitis

- Recurrence rate
- Harms of treatment (including but not limited to pain, dermatologic complications, bleeding, and infection)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) (see the "Availability of Companion Documents" field).

The investigators searched MEDLINE, EMBASE, CINAHL, EBM Reviews, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the Health Technology Assessment database through February 2014 for studies in English. The primary outcomes of interest for this guideline include complete wound healing and wound size (surface area, volume, and depth) reduction. Additional outcomes include pain, prevention of sepsis, prevention of osteomyelitis, recurrence rate, and harms of treatment (including but not limited to pain, dermatologic complications, bleeding, and infection). Although most studies reported statistical significance of various outcomes, the guideline panel assessed clinically significant changes when evaluating the evidence.

Further details about the methods and inclusion and exclusion criteria applied in the evidence review are available in the full Agency for Healthcare Research and Quality (AHRQ) report and the Supplement (see the "Availability of Companion Documents" field).

Number of Source Documents

One hundred seventy-four studies (182 articles) were included in the synthesis:

- Support surfaces: 24 (26 articles)
- Nutrition: 16 (16 articles)
- Local wound applications: 89 (92 articles)
- Surgery: 6 (6 articles)
- Adjunctive therapies: 39 (42 articles)

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Quality of Evidence

High-Quality Evidence: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change confidence in the estimate of effect.

Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example,

biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on confidence in the estimate of effect and may change the estimate.

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Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

From the included studies, details of the patient population, study design, analysis, follow-up, and results were extracted by a team member and reviewed for accuracy and completeness by an investigator. For comparability across studies, when possible, ulcer stage or grade was translated to the corresponding stage as defined by the National Pressure Ulcer Advisory Panel (see Appendix Table 1 in the systematic review). The investigators rated the quality (risk of bias) of the individual studies and strength of the body of evidence, and results were reviewed by at least 1 other investigator for accuracy, with disagreements being settled by consensus. The American College of Physicians (ACP) staff used an approach adapted from the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* for determining the strength of evidence as "high," "moderate," "low," or "insufficient" on the basis of the design, quantity, size, and quality (risk of bias) of studies, consistency across studies, precision of estimates and directness of evidence.

Data Synthesis and Analysis

Data were synthesized qualitatively with attention to characteristics, such as ulcer grade and location, patient characteristics and settings, and risk of bias of individual studies. ACP staff conducted meta-analyses in selected instances for comparisons examining the outcome of complete wound healing where the number, quality, and homogeneity of studies permitted.

The investigators chose to limit meta-analysis to the outcome of complete wound healing because this was the principal health outcome of interest and because of the wide variability in the measurement of other outcomes, including reduction in wound size. When a meta-analysis was conducted, ACP staff used relative risk as the effect measure. They assessed the presence of statistical heterogeneity among the studies using standard chi-square tests and the magnitude of heterogeneity using the I^2 statistic. ACP staff used random-effects models to account for variation among studies and fixed-effects Mantel-Haenszel models when variation among studies was estimated to be zero. Sensitivity analysis was conducted to assess the effect of quality on combined estimates, and meta-regression was conducted to assess the association of effect measure with study duration. All quantitative analyses were done using STATA, version 11.0 (StataCorp, College Station, Texas).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) (see the "Availability of Companion Documents" field).

This guideline is based on a systematic evidence review, an update of the literature (see the Supplement), and an evidence report sponsored by the Agency for Healthcare Research and Quality (AHRQ) (see the "Availability of Companion Documents" field) that addressed the following key questions:

1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection? Does the comparative effectiveness of treatment strategies differ on the basis of features (anatomical site or severity) of the pressure ulcers, patient characteristics, and health care settings?
2. What are the harms of treatments for pressure ulcers? Do the harms differ on the basis of features (anatomical site or severity) of the pressure ulcers, patient characteristics, and health care settings?

This guideline rates the evidence and recommendations by using the American College of Physicians' (ACP's) guideline grading system (see the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields). Details of the guideline development process can be found in the summary of methods paper (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

The American College of Physicians' Guideline Grading System*

Quality of Evidence	Strength of Recommendation	
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	Benefits Finely Balanced With Risks and Burden
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Insufficient evidence to determine net benefits or risks		

*Adopted from the classification developed by the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) workgroup.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was approved by the American College of Physicians (ACP) Board of Regents on July 26, 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Most studies reported on only 1 outcome each (such as reduction of pressure ulcer size, improved wound healing, or rate of wound healing). Complete wound healing was reported in few studies; intermediate outcomes, such as reduction of wound size and rate of wound healing, were used to assess efficacy of the interventions. Some improvements were seen only in patients with large ulcers (>7 cm). See the section "Benefits and Comparative Effectiveness of Pressure Ulcer Treatment Strategies" in the original guideline document for more information.

See also Table 1 in the original guideline document for descriptions and advantages of the various treatment strategies.

Potential Harms

- Skin irritation, inflammation, tissue damage and maceration were the most commonly reported harms for various dressings and topical therapies.
- The most common adverse effect reported with electrical stimulation was skin irritation. Frail elderly patients had more adverse events associated with electrical stimulation than younger patients.
- The most commonly reported harm from surgery was dehiscence. Dehiscence was more common if bone was removed during the surgery, and patients with ischial ulcers had higher complication rates than those with sacral or trochanteric ulcers.
- See the sections "Harms of Pressure Ulcer Treatment Strategies" and "Harms of Pressure Ulcer Treatment Based on Pressure Ulcer Features, Patient Characteristics and Health Care Settings" in the original guideline document for more information.

Qualifying Statements

Qualifying Statements

- Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.
- The authors of this article are responsible for its contents, including any clinical or treatment recommendations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Patient Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Mar 3

Guideline Developer(s)

American College of Physicians - Medical Specialty Society

Source(s) of Funding

Financial support for the development of this guideline comes exclusively from the American College of Physicians (ACP) operating budget.

Guideline Committee

Clinical Guidelines Committee of the American College of Physicians

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Authors followed the policy regarding conflicts of interest described at www.annals.org/article.aspx?articleid=745942 . Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-1567 . A record of conflicts of interest is kept for each Clinical Guidelines Committee meeting and conference call and can be viewed at www.acponline.org/clinical_information/guidelines/guidelines/conflicts_cgc.htm .

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Availability of Companion Documents

The following are available:

- Smith MEB, Totten A, Hickam DH, Fu R, Wasson N, Rahman B, Motu'apuaka M, Saha S. Pressure ulcer treatment strategies: a systematic comparative effectiveness review. *Ann Intern Med*. 2013 Jul 2;159(1):39-50. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .
- Pressure ulcer treatment strategies: update to a comparative effectiveness review. Supplement. 2015. 21 p. Electronic copies: [Annals of Internal Medicine Web site](#) .
- Saha S, Smith MEB, Totten A, Fu R, Wasson N, Rahman B, Motu'apuaka M, Hickam DH. Pressure ulcer treatment strategies: comparative effectiveness. Comparative effectiveness review no. 90. (Prepared by the Oregon Evidence-based Practice Center under Contract No. 290-2007-10057-I.) AHRQ Publication No. 13-EHC003-EF. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 May. 488 p. Electronic copies: Available from the [Agency for Healthcare Research and Quality \(AHRQ\) Web site](#) .
- Qaseem A, Snow V, Owens DK, Shekelle P. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med*. 2010 Aug 3;153(3):194-199. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

A collection of Recommendation Summaries for all current American College of Physicians Clinical Guidelines is now available for mobile devices from the [ACP Web site](#) .

A continuing medical education (CME) activity is available from the [Annals of Internal Medicine Web site](#) .

Patient Resources

The following is available:

- Summaries for patients. Treatment of pressure ulcers. Ann Intern Med 2015 Mar 3;162(5):I-38. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC Status

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